(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45)

Donald S. Clark,

Secretary.

[FR Doc. 97–1233 Filed 1–16–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Safety and Occupational Health Study Section (SOHSS), National Institute for Occupational Safety and Health (NIOSH); Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting:

Name: Safety and Occupational Health Study Section (SOHSS), National Institute for Occupational Safety and Health (NIOSH).

Time and Date: 8 a.m.-5 p.m., February 4-5, 1997.

Place: Terrace Garden Hotel, Magnolia Room, Terrace Meeting Level Access, 3405 Lenox Road, NE, Atlanta, Georgia 30326.

Status: The meeting will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Pub. L. 92–463. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Purpose: The Safety and Occupational Health Study Section will review, discuss and evaluate grant applications in response to NIOSH's standard grants review and funding cycles pertaining to research issues in occupational safety and health and allied areas.

It is the intent of NIOSH to support broad based research endeavors in keeping with the Institute's program goals which will lead to improved understanding and appreciation of the magnitude of the aggregate health burden associated with occupational injuries and illnesses, as well as to support more focused research projects which will lead to improvements in the delivery of occupational safety and health services and the prevention of work-related injury and illness.

Research funded will examine and evaluate current and emerging problems in occupational safety and health in a variety of settings for health and injured workers.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Pervis C. Major, Ph.D., Scientific Review Administrator, Office of Extramural Coordination and Special Projects, Office of the Director, NIOSH, 1095 Willowdale Road, Morgantown, West Virginia 26505. Telephone 304/285–5979.

Dated: January 13, 1997.

Nancy C. Hirsch,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–1208 Filed 1–16–97; 8:45 am]
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Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HF (Food and Drug Administration) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, and 56 FR 29484, June 27, 1991, as amended most recently in pertinent part 60 FR 53379, October 13, 1995) is amended to reflect an organizational change in the Office of Testing and Research and the Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER), in the Food and Drug Administration (FDA).

CDER believes this organizational change will improve operations management and strengthen the existing research and testing structure to more effectively accomplish the Center's mission.

Under section HF–B, Organization:
1. Delete the subparagraphs under the Chemistry Policy Staff (HFNS1), Office of Pharmaceutical Science and insert the following new subparagraphs under Product Quality Support Staff (HFNS1), reading as follows:

Product Quality Support Staff (HFNS1). Manages and facilitates the development, review, coordination, dissemination, organization, and implementation of new chemistry manufacturing policies, procedures, and guidelines related to chemistry and microbiology reviews of new and generic drug applications.

Performs assessments of environmental impact of actions within the drug approval system which may significantly affect the quality of the human environment.

Performs quality assurance and quality control functions for chemistry reviews of both new and generic drug applications.

Provides support for the operations of quality expert working groups or committees focused on the chemistry

manufacturing control technical aspects of the drug review process.

Provides necessary training for chemists, as appropriate.

Develops and implements policies and procedures in support of compendial operations and directs appropriate programs related to compendial initiatives.

2. Delete the subparagraphs under the Formulation Research Staff (HFNS2), Office of Pharmaceutical Science (HFNS) in its entirety.

3. Delete the subparagraphs under the Office Testing and Research (HFNSD) in its entirety and insert new subparagraphs reading as follows:

Office of Testing and Research (HFNSD). Conducts research and develops scientific standards on the composition, quality, safety, and effectiveness of human drug products.

Directs the FDA insulin certification program.

Directs large scale drug quality surveillance activities for the Center as required by regulations.

Conducts and coordinates basic and applied research.

Provides scientific training for new employees through the development and coordination of Staff College programs.

Sponsors cooperative universitybased and industry-linked education programs for postdoctoral traineeships and sabbatical programs. Initiates and coordinates the holding of scientific workshops.

In coordination with the Office of the Commissioner, educates the public on Center and Agency policy and activities.

4. Insert the following new subparagraphs under the Regulatory Research and Analysis Staff (HFNSD-1), Office of Testing and Research (HFNSD) reading as follows:

Regulatory Research and Analysis Staff (HFNSD-1). Serves as the scientific and regulatory liaison to the FDA National Center for Toxicological Research, the National Institute of Environmental Health Sciences National Toxicology Program and other Federal agencies. Coordinates Center-sponsored and Center-related research and communicates scientific information to the Office of Review Management, the Pharmacology/Toxicology Coordinating Committee and the Center's review divisions.

Establishes and maintains a computerized toxicology knowledge database using data derived from Center files in areas such as carcinogenicity, reproductive toxicity, developmental toxicity and genotoxicity. Application of this resource includes regulatory review support, international harmonization,